

## AMENDMENTS

### In The Specification:

Page 1, replace the Title with the following new title: METHOD OF PRODUCING TISSUE BY PLACING A MOLDING SUPPORT WITHIN A BODY CAVITY

Page 2, amend paragraph [0008] as follows:

[0008] For these reasons and because autologous grafts are not always available, attempts have been made to produce synthetic vascular prostheses. The first synthetic vascular prosthesis was made of Vinyon-N and was implanted into a patient in the late 1940's. The patient died 30 minutes after the operation. Replacements have been made with nylon, then later with polytetrafluoroethylene (TEFLON) Teflon and polyethylene terephthalate (DACRON) Daeron. Nylon was found to lose most of its tensile strength after a brief period of implantation leading to aneurysmal dilation and graft rupture. Although both polyethylene terephthalate (DACRON) Daeron and polytetrafluoroethylene (TEFLON) Teflon fabric grafts perform reasonably satisfactorily in high flow, low resistance conditions such as in the aorta, iliac and proximal femoral arteries, neither of these two materials is satisfactory for small caliber arterial reconstructions. Such grafts are compounded by graft failures from stenosis at the anastomotic sites and excessive intimal hyperplasia. These complications are associated with graft thrombogenicity, poor healing and lack of compliance.

Page 3, amend paragraph [0011] as follows:

[0011] Tissue-polymer prostheses are available which incorporate a combination of tissue and synthetic material in the form of an integral composite. In one form, silicone mandrels covered with polyethylene terephthalate (DACRON) Daeron mesh are implanted beneath the cutaneous trunci muscles of sheep where they become encapsulated with ovine collagen (Koch *et al.*, *Aust NZ J Surg* 67:637-639, 1997 [[1997]]). The tubes are then excised and trimmed of

excess fat and connective tissue is then fixed with glutaraldehyde. The silicone mandrel is then removed leaving the fibre-reinforced tube which, after sterilization, is stored in ethanol (Edwards and Roberts, *Clin Mater* 9:211-223, 1992). Although this prosthetic device has been successfully used, it does suffer the disadvantage of lacking elastin, an important component to prevent aneurysmal and dilatory changes from stretching both the collagen and mesh components. Furthermore, the prosthetic device uses glutaraldehyde and this has the propensity to induce non-specific calcification of the implanted device.

Page 4, amend paragraph [0018] as follows:

[0018] Accordingly, the foreign body such as a tube is generally separated from [[for]] the support but a biodegradable matrix generally remains associated with the tissue until it dissolves or breaks down. In an alternative embodiment, the foreign body such as a tube is the biodegradable matrix. Tissue for vascular transplantation may or may not need to be everted.

Page 11, amend paragraph [0062] as follows:

[0062] In one embodiment, the tube is a solid tube. In another embodiment, the tube is in tubular mesh form or a spring-like. Where a particular shape is required, these may be in planer ovoid, round, ~~tubuler~~ tubular, elongated form amongst other forms.

Page 13, amend paragraph [0074] as follows:

[0074] In one preferred embodiment, a Tenckhoff catheter or its functional equivalent is used. This may have a single or double cuff of polyethylene terephthalate (DACRON) ~~Dacron~~ to prevent migration of bacteria and, hence, peritonitis when used in the peritoneal cavity, and may be used with or without silicon discs to hold the omentum and bowel away from the tubing. Conveniently catheters are inserted into the peritoneal cavity over a guide wire through an incision, generally after first infusing with dextrose dialysis solution. The cuff is then sewn in place in the peritoneum and an adapter attached to the external portion of the catheter. This allows peritoneal drainage or the continued addition of fluid. The catheter is surgically removed

after a suitable time (e.g. 1-10 weeks such as 2-3 weeks) without damaging the granulation tissue capsule.

Page 15, amend paragraph [0087] as follows:

[0087] The molding ~~moulding~~ support may be any material including polymers such as cellulose, polyacrylamide, nylon, polytetrafluoroethylene (TEFLON) ~~Teflon~~, polyethylene terephthalate (DACRON) ~~Daeron~~, polystyrene, polyvinyl chloride, polypropylene, silastic tubing and polytetrafluoroethylene. As indicated above, it may also be biodegradable. The use of glass is also contemplated by the present invention but is not a preferred molding ~~moulding~~ support. Reference to “tubular molding” is not to be taken as limiting the molding ~~moulding~~ to a hollow tube. The present invention also contemplates a molding ~~moulding~~ support in the form of a filament such as a solid fibre. A biodegradable mesh or scaffold such as polyglycolic acid (DEXON) ~~Dexon~~™ mesh is a particularly preferred material either as the foreign body or being part of, such as, surrounding the foreign body.

Page 20, amend paragraph [0112] as follows:

[0112] Twenty male adult Wistar rats were anaesthetized with 2.5% v/v (O<sub>2</sub>) halothane. A 20 mm incision was made in the shaved abdominal wall and a variety of objects – plastic silastic tubing (inner diameter range from 0.5-5 mm), glass rod, expanded ~~polytetrafluoroethelene~~ polytetrafluoroethylene (ePTFE) graft (inner diameter 5 mm) and polyethylene terephthalate (DACRON) ~~Daeron~~ graft (inner diameter 6 mm) – inserted inside the peritoneal cavity (see FIG. 1) then the incision closed by 8 interrupted sutures (10-0 Dexon silk). For comparison with previous studies, 10 ml boiled (rabbit) blood clot was inserted into some rats. Only one type of object was used per animal. Animals were divided into four groups (labelled Groups 1 to 4) corresponding to the length of time the foreign body remained inside the peritoneal cavity (Weeks 1 to 4, respectively).

Page 20, amend paragraphs [0116] and [0117] as follows:

[0116] Polyethylene terephthalate (DACRON) ~~Dacron~~ graft was also found to be not preferred as no organized pattern was found around the graft. Instead, there was a rather [[a]] haphazard-like arrangement that penetrated the graft material making it difficult to remove from the granulation tissue without tearing the tissue.

[0117] When ePTFE graft was implanted into the peritoneal cavity highly organized concentric layering of collagen and  $\alpha$ -actin positive cells occurred. The main drawback with the ePTFE graft was the ease with which it adhered to peritoneal fat bodies (omentum/mesentery). Subsequently, a high degree of vascularization was found on these grafts. As it was critical for this study for the material to remain floating at all times, these grafts were rejected. As with the polyethylene terephthalate (DACRON) ~~Dacron~~, difficulty also arose during separation of the granulation tissue from the ePTFE graft, with large tears often occurring.

Page 37, amend paragraph [0203] as follows:

[0203] Improved ways to implant and access the molding ~~moulding~~ are tested using access devices designed for human peritoneal dialysis. Sterile silastic Tenckhoff catheters (Quinton Instrument Co., USA) with a single or double cuff of polyethylene terephthalate (DACRON) ~~Dacron~~ to prevent migration of bacteria and hence peritonitis, and used with or without silicon discs to hold the omentum and bowel away from the tubing. Cut-down versions of these catheters are inserted into the rabbit peritoneal cavity over a guidewire through a small incision, having first infused 15 ml of 1.5% w/v dextrose dialysis solution (plus or minus cytokines/chemokines to increase the number of peritoneal macrophages present). The cuff is sewn in place in the peritoneum, and a Beta-Cap7 adapter attached to the external portion of the catheter. This allows peritoneal drainage or the continued addition of fluid. The catheter is surgically removed after 2 weeks, taking care not to damage the granulation tissue capsule. This

procedure allows more precise and consistent positioning of the “artificial blood vessel” mold ~~mould~~ and alleviates invasive harvesting prior to autologous transplantation.

Page 38, amend paragraph [0212] as follows:

[0212] The pig is of a similar size to humans and has a very similar cardiovascular system, specifically the size and structure of the heart and arteries. Forty pigs (50-1000 Kg) are anaesthetized with intramuscular injection with Ketamine (15 mg/Kg)/Xylazine (1 mg/Kg) then halothane (1-2% v/v) in oxygen via a mask. A sterile silastic Tenckhoff catheter (420 mm long) of outer diameter 5 mm (Quinton7 Instrument Co, USA) with a single or double cuff of polyethylene terephthalate (DACRON) ~~Daeron~~ to prevent migration of bacteria and hence peritonitis, is inserted into the peritoneal cavity over a guidewire through a small incision, having first infused 100 ml of 1.5% w/v dextrose dialysis solution (plus or minus cytokines/chemokines to increase the number of peritoneal macrophages present). The cuff is sewn in place in the peritoneum, and a Beta-Cap7 adapter attached to the external portion of the catheter. This allows the continued addition of fluid, if needed.

Replace the current abstract with the new Abstract set forth in the first Appendix.